CAPITAL NEUROSURGERY, INC.

Kenneth J. Rich, M.D. Timothy B. Garner, M.D.

3320 Wake Forest Road, Suite 410
Raleigh, North Carolina 27609
Telephone: (919) 850-9911
FAX: (919) 790-5524

November 30, 1999

Medtronic Sofamor Danek
1800 Pyramid Place
Memphis, Tennessee 28132

Re: Docket No. 97N-484S

Dear Sirs:

I am writing to make known my feelings about FDA regulations of allograft. Allograft, as you know, is not a medical device. It is a human tissue which is used in some surgical procedures such as fusions. The use of allograft tissue has been well established in the surgical literature. There is no doubt it is an effective and useful material in many operations including anterior cervical fusions. The alternative to allograft is to use one's own hip bone which increases the risk of surgery, the risk of complications due to that surgery, and quite often increases the length of stay a patient experiences because of extreme pain in harvesting bone from one's own hip. To regulate allograft, such as cadaveric bone used in anterior cervical disc surgeries, would adversely affect both the safety and the economics of that surgery. It also may lead to curtailed supply of these bone products which has in the past been quite a problem.

I strongly recommend that allograft material, as has been used in the past, not be regulated as a medical device by the FDA as this can adversely affect patient care.

Sincerely,

Kenneth J. Rich, M.D.

KJR/mmk
dd: 11-30-99
dt: 12-01-99

97N-484S

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